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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/616,622

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

08/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/616,622	Applicant(s) LAFONTAINE, DANIEL M.	
	Examiner DIANE YABUT	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16-29 and 31-41 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13, 16-29 and 31-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 06/04/2009

The examiner acknowledges the amendments made to the claims.

Claims 1-14, 16-29, and 31-41 are pending in the application. Claims 11-12 and 14 are withdrawn from consideration.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-10, 13, 16-29, and 31-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Huebsch et al.** (U.S. Patent No. **6,312,446**) in view of **Redmond et al.** (U.S. Patent No. **6,334,865**) and **Lafontaine et al.** (U.S. Patent No. **5,964,782**).

Huebsch et al. disclose an elongate delivery member **40** and inserting through a body opening a closure component through the delivery member, which includes a collapsible backing or support **200** with proximally facing tissue engaging hooks **270** disposed thereon and being generally conically shaped and having a center portion **216** distally spaced from the periphery of the backing in the non-collapsed, non-deployed position, withdrawing the closure component proximally relative to the opening such that the tissue engaging hooks engage tissue adjacent the opening, applying proximally directed force to a collapse actuator **230** releasably coupled to the collapsible backing

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with a distal end **232** received with and extending distal to a distal aperture **234** of the collapsible backing to thereby collapse the backing to a collapsed, deployed position in which the center portion is moved proximally toward the backing periphery to form a generally disc shape and the hooks engage the tissue, and disconnecting the collapse actuator from the collapsible backing permitting the detachable distal end to pass proximally through the distal aperture and the collapsed backing, and then disconnecting the closure component from the distal end of the delivery member (Figures 5a-5b, 14-17 and 21-22; col. 6, line 43 to col. 7, line 50).

Huebsch et al. disclose disconnecting the collapse actuator detachable distal end **232** from the collapsible backing by rotating the actuator so that it fits through distal aperture **234**, and therefore the collapse actuator is connected or disconnected to the backing depending on its position relative to the distal aperture of the backing (Figures 16-17; col. 6, lines 54-65), which allows for expanding and collapsing of the backing before being detached. However, Huebsch et al. does not disclose the collapse actuator assuming a deformed profile solely in response to a sufficient proximal force applied to the collapse actuator in order to permit the detachable distal end to pass proximally through the distal aperture.

Redmond et al. teach a flexible collapse actuator wire **22** (Figures 1-2; col. 6, lines 5-9) that may have a hook end, as evident in Figure 10, to effectively collapse a closure member. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the withdrawing step of Huebsch et al. with the use of a

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collapse actuator having a deformable distal end, as taught by Redmond et al., to facilitate and simplify retraction of the actuator without the need for rotation.

Huebsch et al. also lack the collapsible backing being made of pile or fabric, wherein the pile engaging hooks engage portions of the pile backing to retain the pile backing in the collapsed position. In addition, although Huebsch et al. teach biocompatible materials (col. 3, line 57 to col. 4, line 17), bioabsorbable materials are not expressly disclosed. The collapse actuator wire having a frangible connection to the distal end of the closure component is also not disclosed.

Lafontaine et al. teach a bioabsorbable pile backing **344** with tissue or adventitia engaging hooks that entangle in the backing located proximal of the hooks as the backing moves from the non-collapsed position to the collapsed position to retain the backing in a collapsed configuration (Figures 34A-34C; col. 17, lines 38-43 and col. 18, lines 24-29). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a bioabsorbable pile backing with hooks that entangle the backing when moved from a non-collapsed to collapsed position, as taught by Lafontaine et al., to Huebsch et al. in order to quickly close the blood vessel while leaving the patient minimally impacted (col. 4, lines 57-67).

Lafontaine et al. teach a wire **334** comprising a frangible, mechanically releasable connection to the distal end of the closure component (col. 20, lines 14-19). Again, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a frangible connection of the collapse actuator to the distal end of

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the closure component in order to quickly and completely close an aperture in the body (col. 20, lines 25-28).

Response to Arguments

3. Applicant's arguments filed 06/04/2009 have been fully considered but they are not persuasive.

4. Applicant argues that Huebsch does not disclose a device that assumes a non-collapsed delivery position wherein the backing has a generally conical shape with a center portion of the backing spaced from a periphery of the backing, but instead a generally cylindrical form as in figure 14. However, this configuration in figure 14 may be considered to be "generally conical" in that either end has a cylindrical shape with a tapering end towards **218**. Also, it is noted that the features upon which applicant relies (i.e., "distally tapering cone") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. In addition, applicant argues that the collapsed position of Huebsch's device resembles a bipyramid rather than a disk. However, either end again as seen in Figure 17 of the device has a flattened circular shape, and therefore reads on this limitation.

Applicant also generally argues that covering the struts of Huebsch with the bioabsorbable backing of Lafontaine would not result in the hooks engaging with the backing. However, the strut elements of Huebsch are meant to be modified by a pile backing having hooks, as taught by Lafontaine above, and therefore the hooks would be

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capable of engaging with the backing when collapsed. The proximally facing tissue engaging hooks **270** do not entangle with the backing when the device is collapsed, as admitted by the examiner, but as mentioned above, the strut elements with the engaging hooks of Huebsch are meant to be modified by the pile backing configuration of Lafontaine, which has hooks that engage the backing when collapsed, and it would have been obvious an obvious modification for quickly close the blood vessel while leaving the patient minimally impacted (col. 4, lines 57-67, Lafontaine).

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **DIANE YABUT** whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734